



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0025]

Okanagan Specialty Fruits, Inc.; Availability of Plant Pest Risk Assessment and Environmental Assessment for Determination of Nonregulated Status of Apples Genetically Engineered to Resist Browning

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service is making available for public comment our plant pest risk assessment and our draft environmental assessment regarding a request from Okanagan Specialty Fruits, Inc., seeking a determination of nonregulated status of apple events designated as events GD743 and GS784, which have been genetically engineered to resist browning. We are soliciting comments on whether these genetically engineered apples are likely to pose a plant pest risk.

DATES: We will consider all comments that we receive on or before [Insert date 30 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to

<http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0025>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2012-0025, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents are also available on the APHIS Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS Petition Number 10-161-01p.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Stankiewicz Gabel, Chief, Biotechnology Environmental Analysis Branch, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3927, email: rebecca.l.stankiewicz-gabel@aphis.usda.gov. To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is

Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS has received a petition (APHIS Petition Number 10-161-01p) from Okanagan Specialty Fruits, Inc., (Okanagan) of British Columbia, Canada, seeking a determination of nonregulated status of apples (Malus x domestica) designated as events GD743 and GS784, which have been genetically engineered to resist browning. The petition stated that these apples are unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process¹ for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice² published in the Federal Register on July 13, 2012, (77 FR 41362-41363, Docket No. APHIS-2012-0025), APHIS announced the availability of the Okanagan petition for public comment. APHIS solicited

¹ On March 6, 2012, APHIS published in the Federal Register (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

² To view the notice, the petition, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025>.

comments on the petition for 60 days ending on September 11, 2012, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

APHIS received 1,939 comments on the petition. Several of these comments included electronic attachments consisting of a consolidated document of many identical or nearly identical letters, for a total of 72,745 comments. Issues raised during the comment period include concerns regarding marketing and economic impacts; cross-pollination; and health, nutrition, and food safety. APHIS has evaluated the issues raised during the comment period and, where appropriate, has provided a discussion of these issues in our environmental assessment (EA).

After public comments are received on a completed petition, APHIS evaluates those comments and then provides a second opportunity for public involvement in our decisionmaking process. According to our public review process (see footnote 1), the second opportunity for public involvement follows one of two approaches, as described below.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises no substantive new issues, APHIS will follow Approach 1 for public involvement. Under Approach 1, APHIS announces in the Federal Register the availability of APHIS' preliminary regulatory determination along with its EA, preliminary finding of no significant impact (FONSI), and its plant pest risk assessment (PPRA) for a 30-day public review period. APHIS will evaluate any information received related to the petition and its supporting documents during the 30-day public review period.

Alternatively, if APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues, APHIS will follow Approach 2. Under Approach 2, APHIS first solicits written comments from the public on a draft EA and PPRA for a 30-day comment period through the publication of a Federal Register notice. Then, after reviewing and evaluating the comments on the draft EA and PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a FONSI or a notice of intent to prepare an environmental impact statement). For this petition, we are using Approach 2.

APHIS has prepared a PPRA to determine if apple events GD743 and GS784 are unlikely to pose a plant pest risk. In section 403 of the Plant Protection Act, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has also prepared a draft EA in which we present two alternatives based on our analysis of data submitted by Okanagan, a review of other scientific data, field tests conducted under APHIS oversight, and comments received on the petition. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of apple events GD743 and GS784 and they would continue to be regulated articles, or (2) make a determination of nonregulated status of apple events GD743 and GS784.

The EA was prepared in accordance with (1) NEPA, as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In accordance with our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments on our PPRA and draft EA regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 30 days from the date of this notice. Copies of the PPRA and draft EA, as well as the previously published petition, are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

As noted previously, after the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. After reviewing and evaluating the comments on the draft EA and PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA. Based on the final EA, APHIS will prepare a NEPA decision document (either a FONSI or a notice of intent to prepare an environmental impact statement).

If a FONSI is reached, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the Federal Register announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 4th day of November 2013.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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